



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/618,361 07/18/00 BALASUBRAMANIAM

A UDC/136R

EXAMINER

HM12/0910

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CINCINNATI OH 45202

KAM.C

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

09/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/618,361

Applicant(s)

BALASUBRAMANIAM ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1, 2, 12-15 and 18-24, drawn to a compound having the formula (R1-A1(R2)-A2-A3-W) and a therapeutic composition comprising the compound, classified in class 514, subclass 18.

Should group I be elected, applicant is required to select one compound (one amino acid sequence). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide.

II. Claims 3, 5, 16 and 18-24, drawn to a compound having the formula (R1-A2(R2)-A3-W) and a therapeutic composition comprising the compound, classified in class 514, subclass 19.

Should group II be elected, applicant is required to select one compound (one amino acid sequence). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide.

III. Claims 4, 6, 17 and 18-24, drawn to a compound having the formula (R1-A1(R2)-A2-W) and a therapeutic composition comprising the compound, classified in class 514, subclass 19.

Should group III be elected, applicant is required to select one compound (one amino acid sequence). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide.

IV. Claims 7, 8 and 18-24, drawn to a compound having a formula selected from the group consisting of Cyclo-(A1-A2), Cyclo-(-A1-A2-A3-), Cyclo-(-A1-A2-A3-A1-A2-A3-), Cyclo-(-A1-A2-A3-A3-A2-A1-), and a therapeutic composition comprising the compound, classified in class 514, subclass 9.

Should group IV be elected, applicant is required to select one compound (one amino acid sequence). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide.

V. Claims 9-11 and 18-24, drawn to a compound having a formula $\text{Ac}-(\text{A1-A2-A3})_n\text{-NH}_2$, and a therapeutic composition comprising the compound, classified in class 514, subclass 17.

Should group V be elected, applicant is required to select one compound (one amino acid sequence). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide.

VI. Claims 25-30, drawn to a method for suppressing an NPY mediated physiological response in a subject comprising administering to the subject a compound of groups I-V, classified in class 514, subclasses 9, 17, 18 and 19.

Should group VI be elected, applicant is required to select one compound (one amino acid sequence). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide.

VII. Claims 31-36, drawn to a method for suppressing an NPY mediated physiological response in a tissue other than the heart in a subject comprising administering to the subject a compound of groups I-V, classified in class 514, subclasses 9, 17, 18 and 19.

Should group VII be elected, applicant is required to select one compound (one amino acid sequence). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide.

VIII. Claims 37-39, drawn to a method for stimulating an NPY mediated physiological response in a subject comprising administering to the subject a compound of groups I-V, classified in class 514, subclasses 9, 17, 18 and 19.

Should group VIII be elected, applicant is required to select one compound (one amino acid sequence). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide.

2. The inventions are distinct, each from the other because of the following reasons:

The products of Inventions I-V are patentably distinct from each other because these products are physically and functionally distinct chemical entities, they have different sequences and different modes of operation.

The products of Invention I-V and the methods of Inventions VI-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention I, II, III, IV or V can be used in an alternate method of Inventions VI-VIII.

The methods of Inventions VI-VIII are patentably distinct from each other because the method steps and outcomes are wholly different between these inventions. For example, the method of Group VI results in suppressing an NPY mediated physiological response such as lower blood pressure while the outcome of Group IV is suppressing an NPY receptor mediated physiological response and Group V results in stimulating an NPY mediated physiological response.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classification and the recognized divergent subject matter, and because Inventions I-VIII require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Insofar as Groups I-VIII are directed to a compound, a therapeutic composition, and methods of use which are defined by a compound with an amino acid sequence that is independent and/or patentably distinct, one from the other. Should Group I, II, III, IV, V, VI, VII or VIII be elected, applicant also needs to select one (1) amino acid sequence. This is not a species election, rather each is held as patentably distinct.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

September 7, 2001

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600